

In-re: Whitehouse

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Please amend claims 10, 13, 15, 17, 22, 23, 26, 30, 33, and 35 as follows:

B2
Sub D1
10. (amended) A method for treating a human patient for coronary artery disease, comprising administering a therapeutically effective amount of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof into one or more coronary vessels or into a peripheral vein in a human patient in need of treatment for said coronary artery disease, said therapeutically effective amount being about 0.2 $\mu\text{g/kg}$ to 48 $\mu\text{g/kg}$ of patient weight.

B3
Sub D3
13. (amended) The method of claim 12, wherein said therapeutically effective amount of a recombinant FGF-2 of SEQ ID NO: 2 or an angiogenically active fragment or mutein thereof is administered into one or more coronary vessels.

B4
Sub D5
15. (amended) The method of claim 12 wherein said therapeutically effective amount of a recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or mutein thereof is administered into a peripheral vein.

B5
Sub D7
17. (amended) A method for treating a human patient for coronary artery disease, comprising[,] administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof into one or more coronary vessels or into a peripheral vein in a human patient in need of treatment for coronary artery disease, said unit dose comprising from about .008 mg to 7.2 mg of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof.

B6
13 22
22. (amended) The method of claim 20, wherein said unit dose is administered into one or more coronary arteries.

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23. (amended) The method of claim 20, wherein said unit dose is administered into a peripheral vein.

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B7
Sub D10
26. (amended) A method for inducing angiogenesis in a heart of a human patient, comprising administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof into one or more coronary vessels or into a peripheral vein in a human patient in need of treatment for coronary artery disease, said unit dose comprising from about .008 mg to 7.2 mg of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof.

B8
Sub D12
30. (amended) A method for treating a human patient for a myocardial infarction, comprising[,] administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof [to] into one or more coronary vessels or [to] into a peripheral vein in said human patient, said unit dose comprising from about .008 mg to 7.2 mg of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof.

B9
24/38
38. (amended) The method of claim 30, wherein said unit dose is administered [to] into a peripheral vein.

B10
Sub D14
35. (amended) A method for providing a human patient with relief from symptoms of angina, comprising administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof [to] into one or more coronary vessels or [to] into a peripheral vein in a human patient in need of relief from symptoms of angina, said unit dose comprising from about 0.008 mg to 7.2 mg of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof.

Please add the following new claims:

B11
Sub D15
--38. The method of claim 10, wherein said therapeutically effective amount of said recombinant FGF-2 of SEQ ID NO: 2 or an angiogenically active fragment or mutein thereof is administered by infusion.

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~~30~~
~~39~~The method of claim ~~17~~⁸, wherein said unit dose is administered by infusion.~~31~~
~~40~~The method of claim ~~26~~¹⁷, wherein said unit dose is administered into one or more coronary vessels.~~32~~
~~41~~The method of claim ~~26~~¹⁷, wherein said unit dose is administered into a peripheral vein.~~33~~
~~42~~The method of claim ~~26~~¹⁷, wherein said unit dose is administered by infusion.~~34~~
~~43~~The method of claim ~~38~~²⁶, wherein said unit dose is administered by infusion.~~44~~

A method for treating a human patient for coronary artery disease, comprising administering a therapeutically effective amount of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof by infusion into one or more coronary vessels or into a peripheral vein in a human patient in need of treatment for said coronary artery disease, said therapeutically effective amount being about 0.2 µg/kg to 48 µg/kg of patient weight.

~~36~~
~~45~~The method of claim ~~44~~³⁵, wherein said recombinant FGF-2 has the amino acid sequence of SEQ ID NO: 2.~~46~~

The method of claim 45, further comprising the step of administering to said human patient about 10 U/kg to 80 U/kg of heparin within about 0 to 30 minutes prior to administering said recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or mutein thereof.

~~47~~

The method of claim 46, wherein said therapeutically effective amount of a recombinant FGF-2 of SEQ ID NO: 2 or an angiogenically active fragment or mutein thereof is administered into one or more coronary vessels.

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48. The method of claim 47, wherein said therapeutically effective amount of a recombinant FGF-2 of SEQ ID NO: 2 or an angiogenically active fragment or mutein thereof is about 24 $\mu\text{g/kg}$ to 48 $\mu\text{g/kg}$.

49. The method of claim 46 wherein said therapeutically effective amount of a recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or mutein thereof is administered into a peripheral vein.

50. The method of claim 49, wherein said therapeutically effective amount of a recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or mutein thereof is about 18 $\mu\text{g/kg}$ to 36 $\mu\text{g/kg}$.

51. A method for treating a human patient for coronary artery disease comprising, administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof by infusion into one or more coronary vessels or into a peripheral vein in a human patient in need of treatment for coronary artery disease, said unit dose comprising from about .008 mg to 7.2 mg of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof.

52. The method of claim 51, wherein said FGF-2 has the amino acid sequence of SEQ ID NO: 2.

44
53. The method of claim 52, wherein said single unit dose produces a therapeutic benefit against coronary artery disease in said human patient that lasts at least four months.

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54. The method of claim 53, wherein said therapeutic benefit in said human patient lasts 6 months.

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46 54. The method of claim *45* 54, wherein said therapeutic benefit is of such magnitude and duration in said human patient such that administration of a second unit dose is not required for about 6 months.

Sub Div *BH* 56. The method of claim 52, wherein said unit dose comprises 0.3 mg to 3.5 mg of a recombinant FGF-2 of SEQ ID NO: 2 or an angiogenically active fragment or mutein thereof.

Cont. Filed 57. The method of claim 51, further comprising the step of administering 10 U/kg to 80 U/kg of heparin to said patient IV or IC about 0 to 30 minutes prior to administering said unit dose.

Sub Div 58. A method for inducing angiogenesis in a heart of a human patient, comprising administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof by infusion into one or more coronary vessels or into a peripheral vein in a human patient in need of treatment for coronary artery disease, said unit dose comprising from about .008 mg to 7.2 mg of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof.

59. The method of claim 58, wherein said FGF-2 has the amino acid sequence of SEQ ID NO: 2.

51 *60* 60. The method of claim *59* wherein said single unit dose produces an improvement in one or more clinical endpoints in said human patient that lasts at least four months.

62 *61* 61. The method of claim *60* 60, wherein said single unit dose produces an improvement in one or more clinical endpoints in said human patient that lasts 6 months.

Sub Div 62. A method for treating a human patient for a myocardial infarction, comprising administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or